Multiplex Assay Development for Arthritis and Musculoskeletal and Skin Diseases

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The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PA-09-127.html

Agency:
Department of Health and Human Services

Release Date:
April 06, 2009
Branch:
n/a

Open Date:
April 06, 2009
Program / Phase / Year:
SBIR / Phase I / 2009

Application Due Date:
September 08, 2012

Solicitation:
PA-09-127

Close Date:
September 08, 2012
Topic Number:
n/a

Description:

Background:

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is interested in SBIR projects to develop multiplex assay methodologies for candidate biomarkers of musculoskeletal, rheumatic and skin diseases. The assay technologies are intended to enable accurate quantitative measurement of multiple candidate biomarkers in small volumes of blood or other body fluid or small biopsies. Many of the diseases within the NIAMS mission are chronic and very complex in nature. The slow development and progression leads to variable spectra of circulating biological markers (usually breakdown or biosynthesis products) that could be used, in combination, as markers of disease state. Biological resources to evaluate these biomarkers are in limited supply and in most cases, non-renewable. Treatment strategies to prevent, arrest or reverse many of these diseases are not available, partly because laboratory tests to predict disease onset or progression or to determine whether therapies may be altering the disease course are limited for many of these diseases. There are expectations of improved diagnosis and prognostication leading toward personalized medicine and targeted treatments based on test results.

Emerging proteomic and genomic technologies have the potential to identify and quantify novel markers in biospecimens that, in combination, can function as biomarkers of the presence or

severity of clinical disease states. Multiplex arrays that simultaneously measure multiple biomarkers can be useful in disease screening and assessing disease risk, severity, and prognosis. Use of such platforms saves time, cost, sample consumption, and reagent volumes while increasing sample throughput relative to single biomarker measurement. The use of single biomarker assays has been widespread for a variety of diseases and found to be limited. A multi-marker approach is more useful in deriving information about the diverse physiologic pathways that contribute to diseases activity.

The field of biomarkers has grown extensively over the past decade in many disease areas, and biomarkers are currently being studied in many academic centers and in industry. However, few single biomarkers have reached the stage of utility in routine clinical practice. With many disorders it is likely that a panel of biomarkers will be required to properly characterize the stage and/or nature of disease. Because of this, the development of high-throughput multiplex assays that are capable of producing highly accurate quantitative data to meet the requirements of the clinical laboratory is needed. At present, few assays for multiple biomarkers are available in the multiplex format that would allow high throughput of a large number of specimens for the clinical proof-of-concept studies that are needed. Most of these are plagued with lack of sensitivity and reproducibility, high variability and correlation of variances, and non-specific binding. The goal of this proposal is to develop multiplex assay platforms that overcome the above limitations. These platforms can be antibody or other capture method based but must be scalable and amenable to high throughput formats. Diseases that have a mixed course of progression would benefit greatly from easy characterization of a wide spectrum of biomarkers. Examples include but are not limited to osteoarthritis, rheumatoid arthritis, SLE, psoriasis, psoriatic arthritis, ankylosing spondylitis, and development of implant wear following hip and knee replacement surgeries. It is critical that these new assays are standardized and validated against existing individual assays and show clinically relevant response to treatments.

Objectives:

The NIAMS seeks projects to apply state-of-the-art multiplex technologies for the measurement of multiple candidate biomarkers in small volumes of body fluid or small tissue biopsies. New technologies are now available that simultaneously identify a wide spectrum of biomarkers and save time and costs. Successful applicants will provide the types of technology platforms used for the assay, the types of molecules the assay can detect (protein, RNA, DNA, etc.), the ability of the assay to precisely quantify multiple biomarker candidates in small quantities of biospecimens, and the ability to incorporate new candidate biomarkers into the assay as they become available.

Phase I applications should address initial development and feasibility testing of the multiplex platforms and Phase II applications should be focused on completing the development of the technology for incorporation into the clinic.